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DERWENT-ACC-NO: 1992-273664
DERWENT-WEEK: 199816

TITLE: Catheter guide wire with flexible top end - has base portion made of shape memory alloy of titanium@-nickel@ type contg. carbon

PRIORITY-DATA: 1990JP-0315997 (November 21, 1990)

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PATENT-FAMILY:

	PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
☐	JP 04187159 A	July 3, 1992		006	A61M025/01
☐	JP 2729856 B2	March 18, 1998		005	A61M025/01

INT-CL (IPC): A61L 29/00; A61M 25/01

ABSTRACTED-PUB-NO: JP 04187159A
BASIC-ABSTRACT:

In core material for catheter guide wire comprising top end portion and base portion, the base portion is made of shape memory alloy of TiNi type contg. C. Catheter guide wire is obtd. by coating the core material with synthetic resin. The alloy contains 0.25 to 5.0 at% of C. The base portion is treated under heating at 400deg.C or lower for 1 to 30 mins. and the end portion is treated at 400 to 550deg.C for 1 to 120 mins. The synthetic resin includes polyethylene, PVC, polyester, polypropylene, polyamide, polyurethane, polystyrene, fluoro resin, silicone rubber, and elastomers.

USE/ADVANTAGE - In the catheter guide wire, the top end portion has high flexibilit

Previous Doc Next Doc Go to Doc#

Notes:
1. Untranslatable words are replaced with asterisks (****).
2. Texts in the figures are not translated and shown as it is.

Translated: 02:44:26 JST 10/21/2006
Dictionary: Last updated 09/29/2006 / Priority:

CLAIMS

(57) [Claim(s)]

[Claim 1] In the core material of the catheter guide wire which it has, the tip part mutually constituted by one and a ground substance part [said ground substance part] 0.25 - 5.0at% of C, and nickel with which a total amount with this C and nickel becomes more than 50.0at%, Consist of an alloy which has the composition which consists of Ti substantially, and aging treatment of the remainder is carried out and this aging treatment in 200-600 degrees C and the range for 0.5 to 100 minutes The core material of the catheter guide wire characterized by carrying out in a selected temperature and time and being given superelastic [desired rigidity and superelastic / desired] in order to acquire desired rigidity.

[Claim 2] In the core material of the catheter guide wire which has the tip part mutually constituted by one and a ground substance part The part which is formed by the TiNi shape memory alloy line containing C work hardened, and constitutes said ground substance part at the temperature below 400 degrees C [with the heat treatment for 1 to 30 minutes] The core material of the catheter guide wire characterized by giving twist convectivity and pliability being given by the heat treatment for 1 to 120 minutes at the temperature whose part which constitutes said tip part is 400-550 degrees C.

[Claim 3] The catheter guide wire which covers a synthetic resin to the core material of a catheter guide wire according to claim 1 or 2, and is characterized by things.

DETAILED DESCRIPTION

[Detailed Description of the Invention]

[Industrial Application]

This invention relates to the core material of a catheter guide wire and catheter guide wire which are a medical department instrument implement.

[Description of the Prior Art]

Generally, after being introduced in a blood vessel from the cell DINGA needle which ****(ed) from the blood vessel part, a catheter guide wire removes a cell DINGA needle from a guide wire, and to the purpose part in **** of a subject, especially a blood vessel It is the medical department instrument implement used in order to precede with a catheter and to guide a catheter.

[for this reason, the core material of a catheter guide wire] It is formed from the tip part which assumes complicated form, and the ground substance part which assumes line form, and sets to living body temperature (**37 degree C). To have the elastic characteristic which reversible form with the load and removal of modification stress including the introduction to a blood vessel and the twist generated at the time of movement is needed. [absorption and discharge of reversible energy, and] [modification and recovering]

As a core material which makes these characteristics hold, the thing which consists of a coil-like stainless steel line or piano wire, or the thing made from a mono-filament-like plastic was used conventionally. Furthermore, these days, the thing using the superelastic function of the alloy of TiNi is coming to be used widely. (JP,S60-63066,A) .

It is known that TiNi and a TiNiX (X=Fe, Cu, Cr, V, --) alloy show a remarkable shape memory effect along with the reverse transformation of a thermoelasticity type martensitic transformation. Moreover, it is also known well that superelastic [which shows an action like rubber by the same principle] is shown collectively.

Furthermore, as for this invention persons, it is found out that a TiNi alloy cannot spoil the characteristic which an essential TiNi alloy has, but can be useful for an improvement of the shape memory characteristic, especially a reversible shape memory effect on the contrary with addition of C. (Tohoku University ******** S.57.6, the 38th volume, and JP,S63-11636,A)

[Problem(s) to be Solved by the Invention]

However, using a TiNi alloy for the core material of a guide wire had the difficulty that a feeling of rigidity is missing compared with the conventional stainless steel line etc., while the pliability which is rich in the outstanding stability was shown. For this reason, it may be difficult to resist power, such as contraction of a blood vessel, and to lead a guide wire to the part of a request in the living body, and it was obliged to the restrictions on a use.

Then, there is a technical technical problem of this invention in offering the catheter guide wire equipped with the core material of a catheter guide wire and it which were made to hold the same elasticity as the conventional TiNi alloy line in a tip part at living body temperature (**37 degree C) at least, and gave sufficient rigidity for a ground substance part.

[The means for solving a technical problem]

According to this invention, in the core material of the catheter guide wire which it has, the tip part mutually constituted by one and a ground substance part [said ground substance part] 0.25 - 5.0at% of C, and nickel with which a total amount with this C and nickel becomes more

than 50.0at%, Consist of an alloy which has the composition which consists of Ti substantially, and aging treatment of the remainder is carried out and this aging treatment in 200-600 degrees C and the range for 0.5 to 100 minutes In order to acquire desired rigidity, the core material of the catheter guide wire characterized by carrying out in a selected temperature and time and being given superelastic [desired rigidity and superelastic / desired] is obtained. Moreover, according to this invention, it sets to the core material of the catheter guide wire which has the tip part mutually constituted by one and a ground substance part. The part which is formed by the TiNi shape memory alloy line containing C work hardened, and constitutes said ground substance part at the temperature below 400 degrees C [with the heat treatment for 1 to 30 minutes] The core material of the catheter guide wire characterized by giving twist convectivity and pliability being given by the heat treatment for 1 to 120 minutes at the temperature whose part which constitutes said tip part is 400-550 degrees C is obtained. Furthermore, according to this invention, the catheter guide wire which covers a synthetic resin to the above mentioned core material of one of catheter guide wires, and is characterized by things is obtained.

Generally, if C is added into a TiNi alloy, react with C in a matrix, TiC is made to mainly generate, and reducing the transformation temperature of an alloy is known. However, it seems that this invention is attained when C addition not only only reduces the transformation temperature of an alloy, but TiC fiber-ized by processing is connected with the improvement of mechanical properties. Moreover, in order to acquire superelastic [at at least 37 degrees C] with a TiNi alloy, the Nakama ** needs to appear with the prescription temperature of 600 degrees C or less. Here, the heat treatment which deposits ****** different [aging treatment before] from aging treatment is called. Moreover, if temperature is raised from low temperature in the case of a TiNi alloy, it will usually change from the single **** structure which is a hypothermic phase to B-2 structure which is ******. However, like this invention, if an unusual appearance is deposited by aging treatment, the ****** structure which is the Nakama ** by the time it changes from single **** structure to B-2 structure will appear. When depending on the prescription after solution treatment, nickel concentration is 50.0at% necessity at least. Moreover, when based on the prescription after work hardening, nickel concentration is good at more than 49.0at%. In the aging treatment which is easy to acquire superelastic [about 500 more-degree C / comparatively good], as for nickel, 50.2at% is needed at least. The conditions same at least also about the C addition TiNi system alloy used for this invention as a TiNi alloy are required. However, according to the transformation temperature fall effect by C addition, if the total amount of nickel+C is more than 50.0at%, it will be obtained by superelastic [good]. The amount of C addition required in order to demonstrate these effects is 0.5 - 5.0at%. That is, less than [0.5at%], the addition effect is thin, and if 5.0at% is exceeded, the problem of processing will become large. Moreover, when

prescription temperature becomes having made prescription temperature and time into 1 to 30 minutes at less than 400 degrees C highly in a ground substance part, rigidity is for showing a fall tendency and not satisfying the purpose of this invention. It is not necessary to necessarily fix prescription time in 1 to 30 minutes, if it is 200 degrees C, and it is 600 degrees C, at least 0.5 minute is possible for 100 minutes, but said prescription conditions are appropriate practical. Moreover, it was considered as the range practical also about the pliability of a tip part, and it is not necessary to necessarily satisfy this condition. That is, it is obtained at 350 degrees C for 200 hours, and pliability is acquired also according to a for [2 minutes] grade at 600 degrees C.

[Example]

The example of this invention is explained with reference to Drawings below.

between heat, by cold work, the TiNi system alloy obtained by the dissolving method was processed to 0.7min(s), and cold work was carried out to 0.50mm in diameter after the solution treatment (the following -- the same) of 950 degree-Cx10min. The elastic characteristic [in / in some obtained wire rods / after heat treatment of 300 degree-Cx5min and 500 degree-Cx30min and / 37 degrees C] was pulled 3%, and it measured by the tensile test in the bottom.

Fig. 1 is a figure showing the relation between the stress value of the TiNi system alloy expressed with the formula of Ti50-x/2nickel50-x/2Cx, and Ti49-x/2nickel51-x/2Cx (x= 0, 1, 2, 3) which is extended 2% and comes out, and the amount of C addition. Curvilinear [in a figure] ** shows the stress value of the aging treatment material of 300 degree-Cx5min of Ti50-xNi50-xCx, curvilinear ** shows the stress value of 500 degree-Cx30min aging treatment material, and curvilinear ** The stress value of the aging treatment material of 300 degree-Cx5min of Ti49nickel51-xCx, Although curvilinear ** shows the stress value of the aging treatment material of 500 degree-Cx30min, respectively, a stress value shows an upward tendency to the amount of C addition, and ** also about which system. In low-temperature aging treatment curvilinear ** and ** of 300 degree-Cx5min, the effect is seen in particular notably.

This showed that it was possible to become improvable [the remarkable increase in stress of rigidity, i.e., a feeling] by low-temperature prescription, and to have the rigidity more than level equivalent conventionally by about 500-degree C prescription, when C was added into the TiNi alloy. Moreover, Fig. 2 shows the stress distortion curve at 37 degrees C of 10 minutes, 30 minutes, 100 minutes, and the sample that carried out prescription for 150 minutes at 500 degrees C of the Ti49nickel50.5C0.5 alloy line which is one of the example alloys of this invention. It turned out that the good superelastic characteristic is acquired also in C addition alloy, and the pliability can be arbitrarily controlled by adjustment of prescription time.

Moreover, as another method, only the ground substance part was made into said C addition

TiNi alloy line which carried out low-temperature prescription, the TiNi system superelastic processing alloy line was used for the tip part, and it became clear that unifying by junction etc. was also possible.

Below, the example of a guide wire is described.

The synthetic resin tunic 4 has almost uniform outer diameters including a tip part, as shown in Fig. 3 . Especially this synthetic resin tunic 4 serves as an almost uniform outer diameter. as a synthetic resin tunic 4, polyethylene, polyvinyl chloride, polyester, polypropylene, polyamide, polyurethane, polystyrene, a fluoro-resin, SHINKONGOMU or an each elastomer, a composite material, etc. are used suitably. And the synthetic resin tunic 4 is flexible to the grade which does not become the hindrance of a curve of an inner core 2, and it is [the outside surface] desirable that it is the smooth surface without unevenness. Moreover, you may coat the synthetic resin tunic 4 with anti-thrombus material, such as anticoagulants, such as HEPARON and urokinase, or silicone rubber, a block copolymer (registered trademark Avco San) of urethane and silicone, and a hydroxyethyl methacrylate styrene copolymer. Moreover, you may reduce the friction nature of a guide wire 1 on the surface by lubricant applications, such as silicone oil, outside forming the synthetic resin tunic 4 with the resin which has the low friction surfaces, such as a fluoro-resin, and the synthetic resin tunic 4. Furthermore, it is desirable to mix the X ray imaging nature substance of the shape of fine powder with a metal simple substance or compounds, such as Ba, W, Bi, and Pb, into the synthetic resin which forms the synthetic resin tunic 4, and the position check of the whole guide wire 1 under introduction in a blood vessel becomes still easier by doing in this way. The synthetic resin tunic 4 has an above almost uniform outer diameter. The tip part may become almost uniform with the narrow diameter not only a completely uniform thing but a little. Thus, the tip of a guide wire can lessen damage with a possibility of giving an intravascular wall, by making even a tip part almost uniform.

The thickness on 0.30-0.64mm and the main part part 2a of a core material 2 of the outer diameter of a synthetic resin tunic is 0.05-0.20mm preferably 0.03-0.30mm 0.25-1.04mm. Moreover, the synthetic resin tunic 4 is put on an adhesion state by the synthetic resin to an inner core 2, and adhering is desirable also in the tip part and end face part of an inner core 2. Moreover, the synthetic resin tunic 4 may be formed with a hollow pipe, and you may fix by an inner core 2, adhesion, or melting fabrication in the tip part of an inner core 2 and a end face part, or a portion with a suitable inner core. And as for the tip (tip of the synthetic resin tunic 4) of a guide wire 1, it is desirable prevention of damage to a blood vessel wall and that it is the curved surface of hemispherical ** further as shown in Fig. 3 for the improvement in operativity of a guide wire 1.

Furthermore, it is desirable that the lubricative substance is being fixed to the surface of the synthetic resin tunic 4. A lubricative substance means the substance which has lubricity at the

time of humidity. Specifically, a water-soluble polymer substance or its derivative exists.
That is, in the diameter at 1800mm and a tip, full length created [the diameter of 0.06mm and the back end] that whose diameter 120mm is reducing in the shape of a taper toward a tip at 0.25mm from the tip as a core material 2 of the guide wire of this example.
Furthermore, the polyurethane which contains tungsten fine powder (about 3-4 micrometers of particle diameter) 45weight % was covered on the external surface of the whole core material so that a whole outer diameter might become almost uniform, and the synthetic resin tunic was made to form in it. And the solution which dissolved the maleic anhydride ethyl ester copolymer was applied to the surface of the synthetic resin tunic formed of the above-mentioned polyurethane so that it might become 5.0 weight % at a tetrahydro franc, the maleic anhydride ethyl ester copolymer was fixed, and the lubricative surface was made to form.
The whole length is [the diameter of about 1800mm and the whole of this guide wire] 0.36mm.

[Effect of the Invention]

According to this invention, the catheter guide wire equipped with the core material of a catheter guide wire and it which raise the twist convectivity of a ground substance part, and have the pliability of a tip part can be offered above.

[Translation done.]

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

Fig. 1 shows the amount of C addition of an alloy line and the relation of stress which are expressed with the form of Ti50-x/2nickel50-x/2Cx, and Ti49-x/2nickel50-x/2Cx (x= 0-3).

Fig. 2 is a figure showing the stress-strain curve of 10 minutes, 30 minutes, 100 minutes, and the sample processed for 150 minutes at 500 degrees C of a Ti49nickel50.5C0.5 alloy line.

Fig. 3 is a side view of the catheter guide wire covered with the synthetic resin concerning this invention.

The inside of a figure, 1 [.... Synthetic resin.] .... A guide wire, 2 .... An inner core, 2a .... An inner core main part part, 4

[Translation done.]